

## § 423.2040

### § 423.2040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) The ALJ hearing office must document all oral requests not to receive written notice of the conference in writing and maintain the documentation in the case files.

(e) At the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the enrollee consents in writing. A record of the conference is made.

(f) The ALJ issues an order stating all agreements and actions resulting from the conference. If the enrollee does not object, the agreements and actions become part of the hearing record and are binding.

### § 423.2042 The administrative record.

(a) *Creating the record.* (1) The ALJ makes a complete record of the evidence, including the hearing proceedings, if any.

(2) The record will include marked as exhibits, the documents used in making the decision under review, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits.

(3) An enrollee may review the record at the hearing, or, if a hearing is not held, at any time before the ALJ's notice of decision is issued.

(4) If a request for review is filed, the complete record, including any record-

## 42 CFR Ch. IV (10-1-10 Edition)

ing of the hearing, is forwarded to the MAC.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) An enrollee may request and receive a copy of all or part of the record, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests all or part of the record from the ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the enrollee's response does not count toward the adjudication deadline.

### § 423.2044 Consolidated hearing before an ALJ.

(a) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ.

(b) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the requests for hearing are combined. In considering the enrollee's request for consolidation, the ALJ must take into account the adjudication deadlines for each case and may require an enrollee to waive the adjudication deadline associated with one or more cases if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(c) The ALJ may also propose on his or her own motion to consolidate two or more cases in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing by sending written notice to the ALJ.

(1) For non-expedited hearings, any request by CMS to participate must be made within 5 calendar days of receipt of the ALJ's notice of the consolidation.

(2) For expedited hearings, any request by CMS to participate must be made within 1 calendar day of receipt of the ALJ's notice of the consolidation. Requests may be made orally or submitted by facsimile to the hearing office.

(e) If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record or a separate decision and record on each issue. The ALJ ensures that any evidence that is common to all appeals and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable.

#### § 423.2046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(1) For expedited hearings, the ALJ issues a written decision within the 10 calendar day adjudication timeframe under § 423.2016(b)(5).

(2) The decision must be based on evidence offered at the hearing or otherwise admitted into the record.

(3) A copy of the decision should be mailed to the enrollee at his or her last known address.

(4) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

(b) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or

scientific evidence used in making the determination;

(2) The procedures for obtaining additional information concerning the decision; and

(3) Notification of the right to appeal the decision to the MAC, including instructions on how to initiate an appeal under this section.

(c) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's decision is a new coverage determination under § 423.566.

(d) *Timing of decision.* For non-expedited hearings, the ALJ issues a decision no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 90 calendar day period is extended as provided in § 423.2016. For expedited hearings, the ALJ issues a decision as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 10 calendar day period is extended as provided in § 423.2016.

(e) *Recommended decision.* An ALJ issues a recommended decision if he or she is directed to do so in a MAC remand order. An ALJ may not issue a recommended decision on his or her own motion. The ALJ mails a copy of the recommended decision to the enrollee at his or her last known address.

#### § 423.2048 The effect of an ALJ's decision.

The decision of the ALJ is binding unless—